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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,770

03/12/2007

Viggo Aaberg Kaern

P71276US0

5690

136 7590 10/03/2008

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EXAMINER

TREYGER, ILYA Y

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

10/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/579,770	KAERN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ILYA Y. TREYGER	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/16/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-22 of the US Patent Application No. 10/579,770 filed 03/12/2007 are presented for examination.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 20-22 provides for the use of device for providing anti-reflux, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 20-22 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).`

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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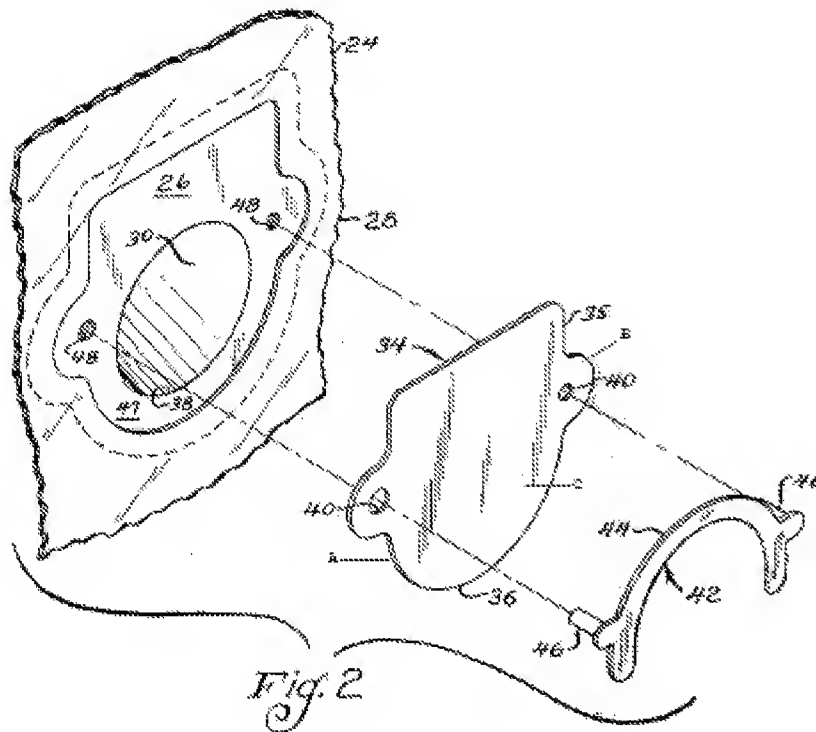
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 6, 7, and 9-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Boedecker (US 3,965,900).

7. In Re claim 1, Boedecker discloses an anti-reflux device (Abstract, line 1) comprising: a wall 28 (Fig. 2) providing a drip chamber 26 (Fig. 2) which is a valve seat, and a valve element 34 (Fig. 2) defining an outer contour A (Fig. 2) formed from a sheet-shaped material, said valve element including a connection portion B (Fig. 2) and a flap portion C (Fig. 2) defining a longitudinal direction extending between the connecting portion and the flap portion, and bores 48 (Fig. 2) which are retaining means for retaining the valve element 34 with respect to the device, said retaining means being integral with the device. The connecting portion B includes apertures 40 (Fig. 2) which are engagement means formed integrally with the valve element for engagement with the retaining means, wherein the valve element is projecting a coherent plane (See Col. 2, lines 46-51, 64; Col. 3, lines 7-13).

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8. In Re claims 2, 10, and 20-22, Boedecker discloses an anti-reflux device (Abstract, line 1) for providing anti-reflux in urine (claim 10) drains from the patient's bladder into the bag for collection (Col. 2, lines 57-59) what means both the body fluid drainage and sampling system.

9. In Re claims 6, 7, and 9, Boedecker discloses a device in which said outer contour A forms a curve defining a continuously advancing function on a respective side of the longitudinal direction (claim 6), and wherein the engagement means 40 are formed within (claim 7) and integrally (claim 9) in said outer contour (claim 7) (See Fig. 2).

10. In Re claim 11, Boedecker discloses the device defining a catheter, a drainage tube connected to the catheter, and the connector to the collection bag (Col. 2, lines 54-59).

In Re claim 12, Boedecker discloses the valve element 34 (Fig. 2) including at least one connecting portion B (Fig. 2) and a flap portion C (Fig. 2) and defining a longitudinal direction

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extending between the connecting portion and the flap portion, and with engagement means 40 (Fig. 2) integrally formed in the valve element (Col. 2, lines 46-51, 64; Col. 3, lines 7-13).

With respect to the limitation regarding that the valve element including the engagement means is manufactured by cutting along a closed line in a sheet-shaped material blank, claim 12 is a product-by-process claim, and since the claimed product is fully disclosed by the reference, the method of the manufacturing the engagement means imbedded in the claim does not impact patentability to the claim.

In Re claims 13 and 16, a device for providing anti-reflux in a body fluid drainage is disclosed as provided, also Boedecker discloses a method of manufacturing a device comprising the following steps:

providing at least one part including a valve seat 26, forming a valve element defining an outer contour from a sheet-shaped material blank, said valve element including at least one connecting portion B and a flap portion C, providing retaining means integral with the device, and bringing the connecting portion into engagement with the retaining means 48, characterized in that engagement means are formed integrally with the valve element, the valve element projecting a coherent plane (See Col. 2, lines 46-51, 64; Col. 3, lines 7-13; Fig. 2) (claim 13), wherein the outer contour is formed along a curve defining a continuously advancing function on a respective side of the longitudinal direction (Fig. 2) (claim 16).

In Re claims 14 and 15, since the valve element 34 is disclosed as being of sheet-like shape and comprising an outer contour in a form of a closed line, Boedecker discloses a method of manufacturing a valve element having a connection portion, a flap portion, and engagement

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means integrally in the valve element comprising the step of cutting the valve element and the engagement means along one closed line in a sheet-shaped material blank (Fig. 2).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boedecker (US 3,965,900).

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14. In Re claim 17, Boedecker discloses the claimed invention discussed above, as applied to claim 13, except for the method in which the outer contour is provided by a cutting operation such as punching, stamping or die-cutting. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the outer contour by a cutting operation such as punching, since it was known in the art that punch is a tool for circular or other piercing (See definition in *The American Heritage® Dictionary of the English Language, Fourth Edition*).

15. In Re claim 18, Boedecker discloses the claimed invention except for the method in which the cutting operation is performed in a rolling operation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the cutting operation in the rolling operation. Examiner takes an Official Notice that the the rolling operation has been conventionally used in the cutting process (See Fig.).

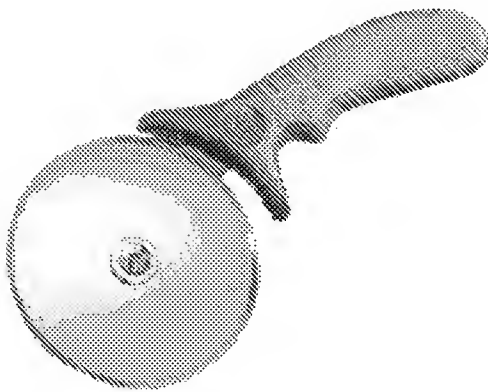


Fig.

16. In Re claim 19, Boedecker discloses the claimed invention except for the method in which the outer contour is provided by cutting by means of laser, water etc. It would have



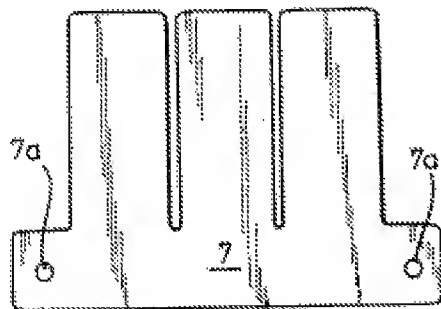
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been obvious to one having ordinary skill in the art at the time the invention was made to provide the outer contour by cutting by means of laser, since it was known in the art that laser has been used for performing the cutting operation, i.e. laser - a device that produces a very narrow intense beam of light, which is used for cutting very hard materials and in surgery etc. [from *light amplification by stimulated emission of radiation*] (See *Collins Essential English Dictionary 2nd Edition*).

17. Claims 3, 4, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boedecker (US 3,965,900) in view of Morone (US 5,027,754).

Boedecker discloses the claimed invention discussed above, but does not expressly disclose the device, wherein the engagement means are slit-shaped (claim 8) or incision-shaped (claims 3 and 4).

Morone teaches the flap valve wherein the valve element is slit- or incision-shaped (since the incision is a variation of slit) (See Fig. 2).



**FIG.2**

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the valve element of Boedecker slit- or incision-shaped, as taught by Morone in order to improve valve element fixation.

***Allowable Subject Matter***

18. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

19. The following is a statement of reasons for the indication of allowable subject matter: The specific limitations of “a hook- shaped section” are not anticipated or made obvious by the prior art of record. For example, the US 3,965,900 teaches a valve element 34 (Fig. 2) defining an outer contour A (Fig. 2) formed from a sheet-shaped material, said valve element including a connection portion B (Fig. 2) and a flap portion C (Fig. 2) defining a longitudinal direction extending between the connecting portion and the flap portion, and bores 48 (Fig. 2) which are retaining means for retaining the valve element 34 with respect to the device, said retaining means being integral with the device.

US 5,027,754 teaches the flap valve wherein the valve element is slit- or incision-shaped (since the incision is a variation of slit) (See Fig. 2).

However US 3,965,900 and US 5,027,754 fail to teach or suggest the specific limitations of a hook- shaped section which improves the fixation of the device.

***Conclusion***

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,784,654 disclose the URINARY COLLECTION SYSTEM AND IMPROVED FEMALE URINARY APPLIANCE. US 5,117,871 disclose the FLAP VALVE. US 3,807,444

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disclose the CHECK VALVE. US 5,027,754 disclose the NON-RETURN VALVE OF THE FLAP TYPE FOR FLOW CONCENTRATION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Treyger/  
Examiner  
AU 3761

/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761